



2008

# The Influence of Partial Body Weight Support on the Muscle Activity in Normal Subjects: On Incline/Decline Surfaces at a Constant Speed

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THE INFLUENCE OF PARTIAL BODY WEIGHT SUPPORT ON THE MUSCLE  
ACTIVITY IN NORMAL SUBJECTS:  
ON INCLINE/DECLINE SURFACES AT A CONSTANT SPEED

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A Scholarly Project  
Submitted to the Graduate Faculty of the  
Department of Physical Therapy School of Medicine  
University of North Dakota  
For the degree of  
Doctor of Physical Therapy

Grand Forks, North Dakota  
May  
2008



This scholarly project, submitted by Kristin Citterman, Leanne Gere, Jessica Price, and Kayley Uvaas in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Faculty Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Cindy Flom-Melamed  
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(Chairperson, Physical Therapy)

## PERMISSION


Title           The influence of partial body weight support on the muscle activity in normal subjects: on incline/decline surfaces at a constant speed.

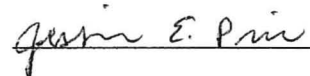
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Degree        Doctor of Physical Therapy

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Date 12/11/07



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## ACKNOWLEDGMENTS

We would like to thank the University of North Dakota Physical Therapy Department for the opportunity to complete this study and for the support and assistance provided throughout our academic careers. A special thank you is extended to Dr. Cindy Flom-Meland, Dr. Dave Relling, and Dr. Renee Mabey for providing the concept, technical support, and statistical analysis needed for the completion of this project. Without the involvement of each of these individuals this study would not have been possible. Also, we would like to recognize our study participants; we appreciate your time and commitment. And finally, thank you to our families and friends for their support and encouragement throughout our physical therapy educations.

## ABSTRACT

**Background and Purpose:** The purpose of this study was to collect data on the effects of incline and decline surfaces, combined with partial body weight support (PBWS), on muscle activity of the lower extremities during treadmill walking for normal subjects. By collecting lower extremity electromyographical (EMG) data we hope that the information may be applied to the development of treatment alternatives or future research options for patients with both neurological and orthopedic dysfunction.

**Methods:** Twenty subjects (14 female, 6 male) were recruited for this study. EMG data was collected for lower extremity muscle activity during conditions of level, incline and decline trials with 20% body weight support and without body weight support.

**Results:** A Repeated-Measures ANOVA was used for comparison of variability between muscle activity in all the conditions. The condition of incline without body weight support was found to have the greatest muscle activity for all muscles with the exception of the biceps femoris in which it had the second greatest muscle activity.

**Conclusion:** By collecting lower extremity EMG data on normal subjects during treadmill ambulation, we hope that the results of this study may be applied to the development of treatment alternatives or future research options. Situations of incline and decline treadmill ambulation, with and without PBWS, should be explored as treatment options for patients with both neurological and orthopedic dysfunction.

## CHAPTER I

### INTRODUCTION

Gait dysfunctions often result from a variety of causes including neurological insults such as stroke, spinal cord and traumatic brain injuries, and may also occur following orthopedic injuries. As a result, from a rehabilitation stand point, one of the key components for patient recovery is gait training to correct or improve these gait dysfunctions and if possible return the patient to independent functional walking.<sup>1, 2, 3</sup> To do this, the main goals of gait training usually focus on improving muscle activation and contractility, and increasing both static and dynamic stability. Many rehabilitation approaches exist; however, they all generally aim to facilitate the relearning of functional movement patterns.<sup>3</sup>

In the past, conventional gait training has consisted of retraining patients in areas of weight bearing, weight shifting, and balance in static positions of the gait cycle. Then, once these tasks have been achieved, patients progress to dynamic locomotor tasks.<sup>4</sup> However, recent research has focused on the use of partial body weight support (PBWS) during gait training as a means to improve gait dysfunctions. Currently, partial body weight support research has mainly investigated the rehabilitation implications for patients with neurological injuries, but some research does exist that applies PBWS treadmill training to patients with orthopedic injuries as well.

In the area of neurologic rehabilitation, it has been proposed that partial body weight support may increase weight-bearing on involved hemiparetic limbs; may

promote symmetry of movement, and facilitate weight shifting while supporting posture during gait training.<sup>3</sup> To support this, several studies have found that treadmill training using PBWS is effective in early stroke rehabilitation for patients who were non-ambulatory; with varied improvements found in areas of gait ability, balance, endurance, and motor function.<sup>1,3,5,6</sup> Also, PBWS treadmill training is considered to be a more task-oriented approach of rehabilitation, leading to faster restoration of gait when compared to other physiotherapy methods used with patients that are non-ambulatory following a stroke.<sup>2,5</sup>

Furthermore, studies using electromyography (EMG), in combination with partial body weight supported treadmill training, have suggested that PBWS may also be valuable for patients with orthopedic impairments. In general, PBWS treadmill ambulation has been considered as a way for patients with orthopedic injuries to decrease loads placed on healing tissues, to conserve energy, and also to reduce pain. Specifically, Colby et al<sup>7</sup> found that PBWS treadmill walking provides a functional exercise which does not compromise muscular activation around the knee joint, with the exception of the vastus medialis at 40% BWS, and lowers energy costs while providing a controlled and safe environment for patients. Thus the study proposed that PBWS treadmill walking may be an effective treatment alternative to use as part of a knee rehabilitation program for patients with orthopedic injuries. In addition, Hesse and colleagues<sup>8</sup> also found that PBWS training appeared to be more effective in returning patients to independent symmetrical walking following total hip arthroplasties.

#### Problem Statement

As research supporting the use of PBWS treadmill training continues to grow,

numerous variables still exist that need further investigation to solidify PBWS as an effective gait training method for patients experiencing orthopedic or neurological gait dysfunctions. Currently, only minimal research exists examining what percentage of total body weight support is appropriate to use, what walking speeds positively influence gait, and the effects incline and decline surfaces have on muscle activity and gait patterns during PBWS treadmill ambulation. Specifically, research is most limited on the effects of incline and decline surface on muscle activity of the lower body when combined with PBWS treadmill walking.

#### Study Purpose and Significance

The purpose of this study was to collect data on the effects of incline and decline surfaces, combined with partial body weight support, on muscle activity of the lower extremities during treadmill walking for normal subjects. By collecting lower extremity EMG data we hope that the information may be applied to the development of treatment alternatives or future research options for both neurological and orthopedic patients. Furthermore, we feel that this study is significant in that it attempts to bridge the gap in applying PBWS treadmill training between orthopedic and neurological patients by providing EMG data expected in “normal” gait patterns on inclined and declined surfaces. We expect to find differences in EMG activity of the lower extremity muscles with unsupported and partial body weight supported walking for and between the following conditions: level walking, inclined walking, and declined walking.

#### Research Question

Is there a difference in EMG activity for the following lower extremity muscles; rectus femoris, gluteus medius, biceps femoris, gastrocnemius, anterior tibialis, and



adductor muscle groups, when weight bearing (full or partial) and surface (level, incline, and decline) conditions are varied during forward treadmill ambulation?

Hypothesis – Null (H<sub>0</sub>) and Alternate (H<sub>A</sub>)

H<sub>0</sub> = During forward treadmill ambulation, there is no significant difference in percent EMG activity between six conditions (level FWB, level PWB, incline FWB, incline PWB, decline FWB, and decline PWB) for the rectus femoris, gluteus medius, biceps femoris, gastrocnemius, anterior tibialis, and adductor muscle groups.

H<sub>A</sub> = During forward treadmill ambulation, there is a significant difference in percent EMG activity between six conditions (level FWB, level PWB, incline FWB, incline PWB, decline FWB, and decline PWB) for the rectus femoris, gluteus medius, biceps femoris, gastrocnemius, anterior tibialis, and adductor muscle groups.

## CHAPTER II

### LITERATURE REVIEW

#### The Gait Cycle

The gait cycle is a time sequence of motion that occurs from initial contact to initial contact of the same foot. The gait cycle can first be broken into two broad phases: stance and swing phase. Stance phase is the period of time when the limb is in contact with the ground and swing phase begins when the foot comes off the ground. Stance phase makes up 60- 62% of the gait cycle and swing phase makes up 38-40% of the gait cycle. The gait cycle can also be further broken down into eight distinctive sub-phases.<sup>9</sup>

1.) Initial Contact (IC): This sub-phase starts the moment when the foot contacts the ground and takes place at 0% of the gait cycle. The primary muscles used at this phase of the gait cycle are the hip extensors, knee flexors, knee extensors, and ankle dorsiflexion.

2.) Loading Response (LR): This sub-phase is when weight is quickly transferred onto the outstretched lower extremity. This is the first period of double- limb support. It takes place from 0-12% of the gait cycle. The primary muscles used at this phase of the gait cycle are the hip extensors, knee flexors, knee extensors, and ankle dorsiflexors. The muscles that are at their peak work load during this phase include the gluteus medius, tensor fascia latae, and adductor magnus.

3.) Mid Stance (MS): During mid stance the body moves over a single, stable limb. This sub-phase takes place from 12-31% of the gait cycle. The hip extensors, hip abductors,

knee flexors, and ankle plantarflexors are active at this phase of the gait cycle.

4.) Terminal Stance (TSt): The body continues to progress over the stance limb during this phase. The body progresses ahead of the limb and weight is transferred to the forefoot. This phase takes place from 31-50% of the gait cycle. The primary muscles working during this phase of the gait cycle are the hip abductors and ankle plantarflexors.

5.) Pre-Swing (PSw): This phase is when rapid unloading occurs and weight is transferred to the contralateral limb. This is the second period of double limb support. This phase takes place from 50-62% of the gait cycle. The primary muscles activated at this point are the hip adductors, knee extensors, and ankle plantarflexors. The rectus femoris is at peak performance during this phase.

6.) Initial Swing (ISw): During this phase the thigh advances as the foot comes off the ground. It takes place during 62-75% of the gait cycle. The muscles active at this time include the hip flexors, hip adductors, knee flexors and extensors, and ankle dorsiflexors. The iliacus, sartorius, and gracilis are working at their peak during this phase.

7.) Mid Swing (MSw): The knee begins to extend and the thigh continues to advance and the foot clears the floor. This phase occurs from 75-87% of the gait cycle. The primary muscles activated are the hip extensors, hip flexors, knee flexors, and ankle dorsiflexors.

8.) Terminal Swing (TSw): The knee extends to except weight that occurs with contact with the ground for initial contact. This phase occurs from 87-100% of the gait cycle. The muscles in the lower extremity that are active during this phase include: hip extensors, hip adductors, knee flexors, knee extensors, and ankle dorsiflexors.

The gait cycle can also be categorized in a more functional capacity. The cycle can then be divided into three functional tasks: weight acceptance, single limb support, and swing limb advancement.<sup>9</sup>

1.) Weight Acceptance (WA): This task would include the initial contact and loading response phases. During this task weight is transferred rapidly onto an outstretched limb. The initial impact from the floor reaction force is absorbed and the body continues to move forward, stability is maintained during this movement. This occurs during the period of double-limb support.

2.) Single Limb Support (SLS): This task includes the mid-stance and terminal stance phases. This is when the body progresses over a single limb. During single limb support, weight is transferred to the front of the foot and the heel comes off the ground.

3.) Swing Limb Advancement (SLA): This task includes pre-swing, initial swing, mid-swing, and terminal swing phases. This task is when the limb is unweighted and the foot comes off the ground and is swinging forward from behind the body.

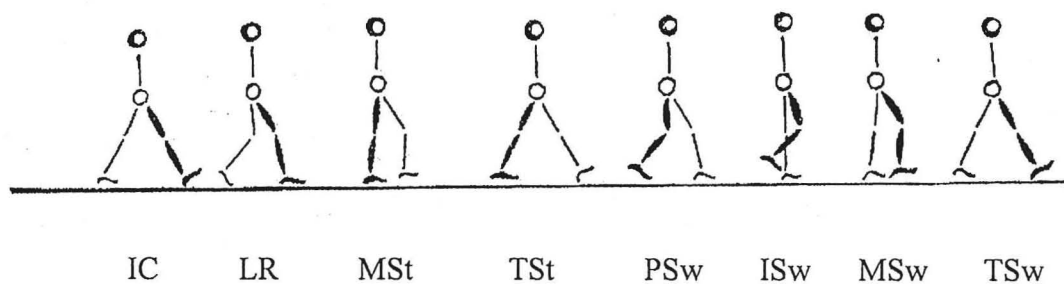


Figure 1. Gait cycle (modified from Ranchos Los Amigos).

## Biomechanics of Gait

There are three major events that happen during the gait cycle which consume energy. These include the control required during forward movement of the limb during deceleration (occurring towards the end of swing phase), initial contact with the ground, and propulsion during push off. The goal of a normal gait pattern is to move with the most efficiency as this requires the least amount of energy expenditure.

The human body's center of mass (COM) is normally located just anterior to the second sacral vertebrae. The body moves the most efficient when there are no deviations from side to side or up and down from the center of mass. It is when deviations start to occur that energy expenditure is increased.

There are five determinants of gait which if utilized correctly will decrease the energy expenditure during ambulation. The first determinant is pelvic rotation in the horizontal plane. When a person walks the pelvis rotates forward on the swinging extremity and backwards during mid-stance. Pelvic rotation is the greatest just before initial contact with a total movement of 3-5 degrees to each side. This allows a person to produce a longer step without changing the center of mass displacement significantly. The second determinant is pelvic tilt in the frontal plane. When the pelvis on the swing leg is lowered, the hip abductors on the other hip are stabilizing the pelvis. When an individual normally ambulates, the pelvis drops anywhere from 4-5 degrees away from the leg in contact with the ground and towards the swing leg. The third determinant is knee flexion at mid-stance, which helps decrease vertical displacement of the center of mass. The fourth determinant of gait is knee-ankle-foot motion which takes place during initial contact and mid-stance of the gait cycle. The combined movement of the knee-

ankle-foot results in an eccentric contraction of ankle plantarflexors and knee flexors. The fifth determinant of gait is physiological valgus of the knee this reduces the lateral displacement of the center of mass during gait.

#### Partial Body Weight Support Treadmill Training (PBWS)

The gait cycle consists of a combination of complex movements that must be synchronized perfectly to allow the individual to walk effectively. The use of PBWS allows individuals with neurological or musculoskeletal injury to perform the combination of these complex movements in a more efficient manner.

There have been multiple studies conducted on the effectiveness of PBWS for patients with neurological conditions, including post cerebral vascular accident (CVA) and spinal cord injury (SCI). There have also been studies conducted on the normal and orthopedic subjects using PBWS. Although there is limited research conducted on the effectiveness of the use of PBWS in patients with orthopedic injuries.

#### Stroke

A cerebral vascular accident (CVA), or stroke, is the number one cause of disability in adults. A stroke is usually a sudden vascular event that results in damage of brain tissue. Hypertension, diabetes mellitus, smoking, and some cardiac diseases such as mitral stenosis and coronary heart disease all increase the risk of having a CVA.

A transient ischemic attack (TIA) is similar to a CVA and can indicate the oncoming of a CVA. A TIA may or may not produce damage to the brain. Individuals that experience a TIA have complete recovery of neurological function in 24 hours.

There are two categories of stroke, ischemic and hemorrhagic. An ischemic stroke is the occlusion by an embolism or thrombosis of a main vessel. The most

common place for an embolism to occur is within the heart. Thrombus formation is typically caused by atrial fibrillation. There are different syndromes associated with an ischemic stroke and dysfunction is dependent on which vessel is affected in the brain. The syndromes can be complete or partial, and are named in reference to the vessel that supplies the area of the brain affected.

A hemorrhagic stroke can be intracerebral, subarachnoid, or subdural. An intracerebral hemorrhage is bleeding from a vessel directly into the brain parenchyma. This is the most deadly type of stroke. A subarachnoid hemorrhage is bleeding from a vessel into the subarachnoid space. These strokes can result from sudden, severe headaches, and are spontaneous. A subdural hemorrhage stroke results from the tearing of the bridging veins between the dural sinus and brain surface. If the amount of blood in the dural space is small, the body can reabsorb the fluid. When there are larger amounts of blood, the fluid can create a lesion in the brain and can compress the brain tissue.

### Impairments Following a Stroke

An impairment is what “evolves as the natural consequence of pathology or disease and are defined as any alteration or deviation from normal in anatomical, physiological, or psychological structures or functions,” <sup>10, p. 374</sup> according to the Nagi model. Impairments are at the neuromuscular, musculoskeletal, cardiopulmonary, and integumentary level. Impairments can be direct, indirect, and/or combined indirect and direct.

Direct impairments from a CVA can include sensation deficits, pain, visual changes, decreased motor function, weakness, changes in tone, abnormal synergy patterns, abnormal reflexes, altered coordination, changes in postural control and balance,

deficits in speech (aphasia), language, and swallowing (dysphagia), changes in emotional status, and bowel and bladder dysfunctions.

Indirect impairments can include loss of range of motion due to contractures, weakness from muscle inactivity, osteoporosis, seizures, hydrocephalus, increased risk for developing a deep vein thrombosis (lack of activity), impaired cardiac output and rhythm disorders, decreased lung volumes, increased risk for aspiration (because of dysphagia), and skin breakdown which can result in decubitus ulcers.

Composite impairments are impairments that occur from both direct and indirect impairments. Decreased endurance and impaired balance are examples of composite impairments.

#### Functional Limitations Following a Stroke

"A functional limitation is the inability of an individual to perform an action or activity in the way it is done by most people, usually as the result of an impairment." <sup>10, p. 375</sup> There are three categories of function according to O'Sullivan & Schmitz, including physical function, psychological function, and social function. Physical function corresponds to activities that are typically performed each day (activities of daily living [ADLs]) such as walking, getting out of bed, climbing stairs, dressing, daily hygiene, and feeding. Psychological function has been divided into two parts: mental function and affective function. O'Sullivan & Schmitz describe mental function as the "intellectual or cognitive abilities of an individual." <sup>10, p. 375</sup> Some of these abilities would include memory, attention, problem solving, and concentration. Affective function "refers to the affective skills and coping strategies needed to deal with the everyday 'hassles' as well as the more traumatic and stressful events each person



encounters over the course of a lifetime.”<sup>10, p. 375</sup> Attitude towards body image, self-esteem, and anxiety are some examples of affective function according to O’Sullivan & Schmitz. Furthermore, social function “refers to an individual’s performance of social roles and obligations.”<sup>10, p. 375</sup> This can include social interaction (visiting a friend), social activity (going to the mall), and social roles made from interpersonal relationships in one’s personal life or work life.

Specific assessments should be given to each patient to determine the functional abilities, quality of life, and impairments of the patient. The Fugl-Meyer Assessment (FMA), Motor Assessment Scale (MAS), Stroke Specific Quality of Life Scale (SS-QOL), National Institutes of Health Stroke Scale (NIHSS), and Stroke Impact Scale are all assessments that can be given to patients that have had a stroke.

### Rehabilitation

Rehabilitation can begin once the patient is medically stable. Earlier mobilization is important and it aids in decreasing the effects of indirect impairments. Patients with moderate to severe impairments may benefit from rehabilitation programs. The Commission on Accreditation of Rehabilitation Facilities (CARF) and the Joint Commission on Accreditation of Healthcare Organizations (JACHO) are certified rehabilitation programs that provide high quality care and must adhere to uniform standards.<sup>10</sup> Patients that are referred to these rehabilitation programs need to be able to tolerate therapy services for three hours a day, five days a week, and from at least two separate rehabilitation disciplines.

Intervention strategies depend on what impairments the patient presents with. However, current research on intervention approaches and strategies should be utilized.

Sensory function, motor function, aerobic capacity, and feeding and swallowing strategies all should be addressed when treating patients following stroke. Sensory function can be treated by presenting different stimuli to the patient's extremities. Treatments for motor function can include flexibility, joint integrity, strengthening, ways to manage spasticity, motor learning (cognitive associative, and autonomous stages), postural control and functional mobility (rolling, supine-to-sit and sit-to-supine, sitting, bridging, sit-to-stand and stand-to-sit, standing and transfers), gait training, and wheelchair mobility.

Studies were reviewed regarding subjects with neurological involvement and the effects of body weight supported treadmill training. A study completed by Dobkin B et al<sup>11</sup> examined 146 subjects with incomplete spinal cord injuries ranging from level C5 to L3. Each subject received 12 weeks of step training either with body weight support on a treadmill or over-ground mobility training. No significant differences were found at the start of the study or after 6 months in walking speed or distance between groups. Therefore, using body weight support training on a treadmill in this study was not found to be more effective in increasing functional walking speeds than defined over-ground mobility training.

In a different study done by Chen G et al<sup>12</sup> six individuals with post-stroke hemiparesis and six non-disabled controls ambulated at matched speeds on a treadmill. Differences were found during gait between the two groups. The main differences were the compensatory strategies used by the subjects who had experienced a stroke and the swing initiation of the involved limb of the subjects who had experienced a stroke.

Additionally, pilot studies were performed on subjects with chronic stroke using

partial body weight during ambulation in a study completed by Trueblood PR.<sup>3</sup>

Ambulating on a level surface, ambulating with partial body weight on a level surface, and ambulating with partial body weight on a treadmill were all compared. Then repeated ambulation with partial body weight on a treadmill was studied. Improvements were made in both gait and balance in the subjects when ambulation with partial body weight on a treadmill was performed.

Furthermore, studies involving subjects with neurological involvement and the effects of body weight supported treadmill training with incline was researched. In a study performed by Werner C et al<sup>13</sup>, inclination of a treadmill for gait training of patients with hemiparetic stroke was investigated. Five different levels of inclination were utilized and EMG, heart rate, and gait cycle were all assessed. The article concluded that gait training on a treadmill with an inclination up to 8% can be beneficial for stroke patients.

#### Subjects with Orthopedic Problems

During our review of the literature, only three articles were found while searching for studies involving patients with orthopedic problems and the utilization of PBWS. Also, we found that there is limited research on the use of PBWS with incline/decline gradients in orthopedic patients and neurological patients. However, Hesse and colleagues<sup>8,14</sup> have found in their research that PBWS is a new promising technique in the rehabilitation of patients after hip arthroplasty.

In one study, Hesse et al<sup>8</sup> examined the effects of PBWS versus traditional physical therapy in 80 patients with unilateral total hip arthroplasty. At the end of the training sessions, the treatment group (PBWS plus traditional physical therapy) had less

hip extension deficits as compared to the control group, 10% greater gait symmetry, stronger hip abductors on the affected side, and greater amplitude of the gluteus medius activity by 41.5%. Patients were also able to abandon their crutches more quickly in the treatment group and the significant differences remained at 3 and 12 months. This study provides support for the use of treadmill training with partial body weight support for patients after total hip arthroplasty. PBWS was shown to be more effective in returning patients to independent symmetrical walking after a total hip arthroplasty.

In a similar study Hesse et al<sup>14</sup> analyzed the gait of patients with hip arthroplasty, walking on the treadmill and also walking on the floor with and without crutches. Nineteen patients post hip arthroplasty, who were able to accomplish full weight bearing (FWB), walked on a treadmill with 15% body weight support and during floor walking with and without crutches at comparable walking speeds. This study concluded that PBWS enables patients post hip arthroplasty to regain a dynamic and symmetrical gait pattern with better activation of the hip abductors on the affected lower extremity as compared to walking with crutches. There was still a higher level of hip abductor activation when the patients walked without crutches but this also resulted in a limping gait pattern.

Finally, in a study by Hunter and colleagues<sup>15</sup> a comparison was made between the energy expenditure of healthy below-knee amputee subjects and healthy able-bodied subjects during PBWS treadmill ambulation in order to determine energy conservation. Subjects walked on a treadmill at a speed of .67(1.5 mph) m/sec and 1.34 m/sec (3.0 mph), during each of the following PBWS trials; full BW, 20% BWS, and 40% BWS. At the end of each trial the subjects rate of perceived exertion (RPE), heart rate (HR), and

VO2 measures were collected. They found significant lower rates of RPE, HR, and VO2 for able-bodied subjects vs. below-knee amputees during all trials. Other results from the study showed both groups demonstrated significantly lower HR and VO2 during at 1.34m/sec with 40% BWS. The results of this study provide preliminary justification for the use of PBWS in gait training for patients with transtibial amputation and reducing energy expenditure.

### General Parameters

There are a large number of body weight support percentages and treadmill speeds combinations that have been used in various studies. The grade of incline/decline of the treadmill also varies from study to study. A variety of body weight support have been used in previous studies, including a range anywhere from 10-75%, but not all of these percentages are practical for the clinical setting.<sup>5,16,17,18</sup> Body weight support levels up to 30% have been shown to closely resemble those of gait kinematics with full body weight. When body weight supports of greater than 30% are used, a patient/client is unable to produce the appropriate forces required for forward propulsion during walking on a treadmill or just on level ground.<sup>5, 16,17,18, 20</sup>

An article published by van Hedel, Tomatis and Muller<sup>20</sup> conducted a study with 20 healthy subjects. They had each subject walk on a treadmill at varying walking speeds and with partial body weight support of 0%, 25%, 50%, and 75%. They were able to conclude from their results, that standards for EMG activity and joint angle trajectories should only be compared when training is done under conditions of velocities higher than 1.56 miles per hour and less than 50% body weight support. If 75% body weight support or speeds of less than 1.56 miles per hour were used, the cadence and stride length of the

subjects' gait was affected.

With the variety of information that we have presented, PBWS treadmill training is becoming a more recognized tool for treating patients with multiple impairments and functional limitations. Using subjects who have no impairments or functional limitations will allow us to determine whether PBWS treadmill training can help maintain proper muscle activation during the gait cycle. The study will additionally present baseline data on PBWS on incline/decline surfaces during ambulation and how it affects muscle activation of the lower extremity.

### CHAPTER III

#### METHODOLOGY

Prior to the initiation of this study, the project proposal was reviewed and approved by the University of North Dakota Institutional Review Board (see Appendix A). The methods used to conduct this study are described in the following chapter.

#### Subjects

Twenty subjects, six male and fourteen female, were recruited from the University of North Dakota student population. This was completed by placing sign-up sheets at the School of Medicine and Health Sciences Department of Physical Therapy student bulletin board, as well as in the University's Memorial Student Union. All subjects were required to be 18 years of age, students at the University of North Dakota, and able to fulfill an hour time commitment for participation in the study. Additionally, subjects had to be able to ambulate independently for at least 20 minutes on a treadmill. Participants were excluded from the study if they had a history of lower extremity orthopedic surgeries or acute (within 8 weeks of study participation) lower extremity injury.

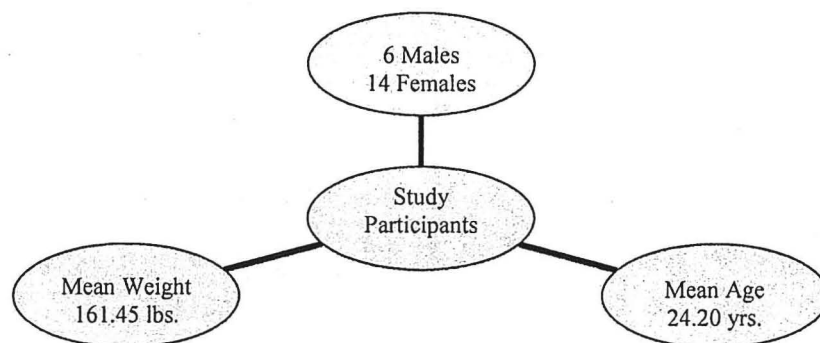


Figure 2. Study participant demographics.

Prior to participation in the study, each subject was given a copy of the informed consent form (Appendix B). Each participant was required to read and sign the consent form indicating understanding of the study and its objectives. Participants had to be able to read and understand the document and be competent and independent in their decision-making. Additionally, participants were provided with a copy of the consent form to retain in the event they had further questions or concerns regarding participation in the study.

### Instrumentation

Surface electrodes were utilized to record electromyographical (EMG) muscle activity. EMG activity was collected with a TeleMyo 900 telemetry unit (Noraxon USA, 13430 North Scottsdale Rd., Scottsdale, AZ 85254). This activity was then transmitted to a TeleMyo 900 receiver and then digitized by an analog digital interface board in Peak Analog Module. The Peak Motus 5 system (Peak Performance, Englewood, CO) was used to store and analyze the EMG data. Final data are presented as percent of normalized EMG activity obtained while the participant was ambulating on level surface, either with or without body weight support.

A LiteGait body weight support system and a Gate Keeper Treadmill were used for the treadmill training. Following the recording of all trials, all subjects' movements were digitized using the Peak Motus software package.

### Procedure

Following reading and signing the informed consent, participants were asked to draw one of two cards. The card drawn signified the order in which the participant would perform incline and decline trials, with a red card drawn indicating incline be performed



first and a black card indicating decline be performed first. Electrode placement sites were determined and marked on the right lower extremity of each subject with a permanent marker according to EMG placement standards.<sup>21</sup> After each area was marked it was prepared, if necessary, by shaving the existing hair with an electric clipper and razor. All participants then had the electrode sites prepared with fine sand paper and cleaned vigorously with rubbing alcohol. Two electrodes were then placed parallel to the muscle fibers at six areas, making sure to maintain a 1-2 millimeter distance between each electrode. The gluteus medius electrodes were placed at the point a proximal third of the distance between the iliac crest and the greater trochanter. The rectus femoris electrodes were located at the midpoint of a line from the anterior superior iliac spine (ASIS) to the superior pole of the patella. The adductor group electrodes were located at half the distance from the pubic symphysis to the medial femoral condyle. Electrodes for the biceps femoris were placed at the midpoint of a line from the ischial tuberosity to the lateral femoral condyle. The lateral gastrocnemius electrodes were located over the muscle belly one-quarter of the distance from the fibular head to the calcaneus. Anterior tibialis electrodes were positioned over the muscle belly one-third of the distance from the inferior pole of the patella to the lateral malleolus. A ground electrode was placed on the fibular head (see Appendix C for electrode placement pictures).

Following electrode placement, the harness for the LiteGait system was applied to the subject using the greater trochanters as a reference point for the location of the bottom belt of the harness. Electrode wires were then attached to the appropriate electrodes and a foot switch was placed inside the shoe under the plantar surface of the right heel of all subjects. The weight of the subject (with equipment donned) was determined using a

standard medical scale and 20% body weight support (BWS) levels were calculated and recorded. All subjects walked on level surface without body weight support to begin their testing. See below for a picture of level surface set-up.

The harness was attached to the support system and each subject was instructed to stand with his/her feet shoulder-width apart in a relaxed standing position to begin and end each trial. While this was being done, a description of how the trials would be conducted was read to the participant, as well as the safety features of the treadmill pointed out. Each subject was also told to keep his/her hands off the treadmill hand rails and to look straight ahead while walking.

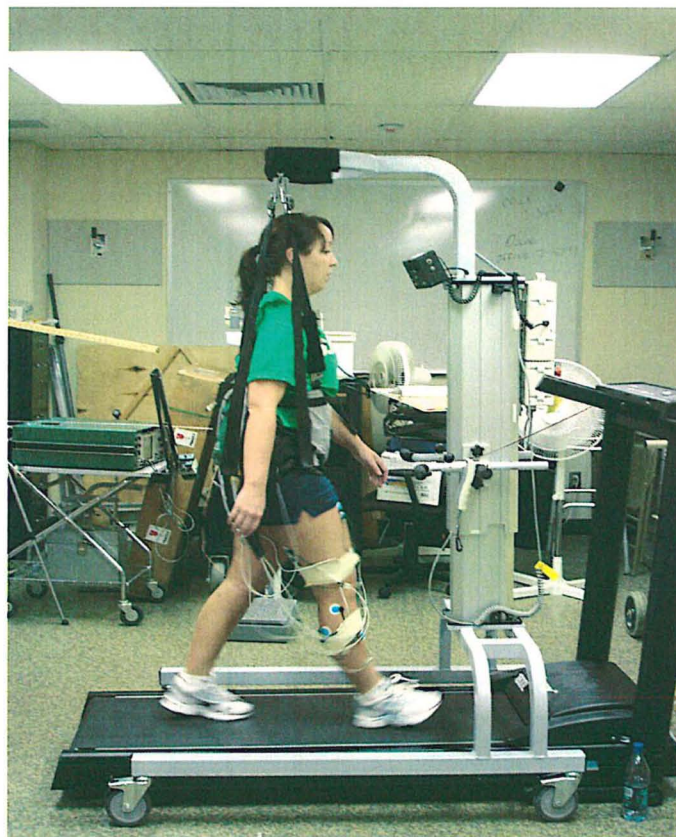


Figure 3. Set-up for the unsupported level surface trial.

During each phase of the study, the subjects walked for three minutes at a speed of 3.0 miles per hour. The first minute was to allow the subject to adjust to the treadmill speed, incline or decline, and BWS or non-BWS situation. During the second and third minutes of walking, data was randomly collected for one 20 second interval during each minute. After each phase, participants were allowed to rest for 1-3 minutes while the incline or decline on the treadmill was adjusted and BWS was either applied or removed. After each subject performed a baseline trial at level surface with no BWS, he/she then performed a baseline trial at level surface with BWS. Incline and decline situations were then applied according to which card the participant had drawn earlier, with no BWS trials always being performed prior to BWS trials. Incline trials were conducted at a grade of 7.1% (4.1° angle from level surface) and decline trials were conducted at a grade of 5.3% (3.0° angle from level surface). Pictures of the set-up for the incline and decline trials follow in Figures 5 and 6. Throughout the course of the trials, the comfort and exertion levels of the subjects were inquired about.

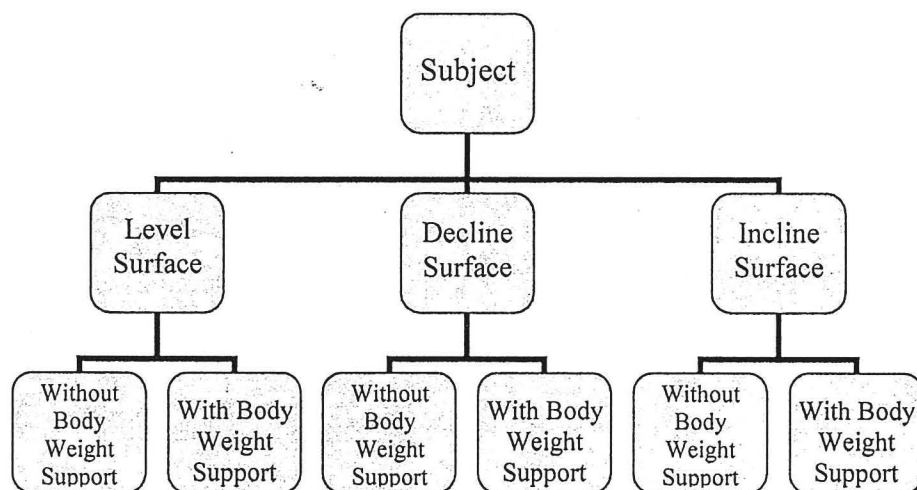


Figure 4. Subject trial design.

As previously mentioned, the EMG activity was collected using the TeleMyo 900 telemetry unit. It was transmitted from the telemetry transmitter to the TeleMyo 900 receiver which was interfaced with an analog to digital interface unit (Peak Performance Inc., Englewood, CO) utilizing a NorBNC board (Noraxon, USA). The EMG files were then imported from the Peak Performance system into the Myoresearch XP software program (Noraxon, USA) using a laptop computer. Using the Myoresearch XP (Noraxon, USA) software program, the EMG data was integrated and smoothed. EMG data was filtered, rectified, and normalized to the treadmill level surface, without BWS trial for each subject. Final data are presented as a percent of normalized EMG activity as an average of three gait cycles at each of the support trials. The EMG data was analyzed using the MyoResearch software package to make comparisons between muscle activity on level surfaces with and without BWS and muscle activity on inclined and declined surfaces with and without BWS. Using the SPSS program (Version 15.0) descriptive and inferential statistics were analyzed using a paired samples t-test and Repeated-Measures ANOVA.



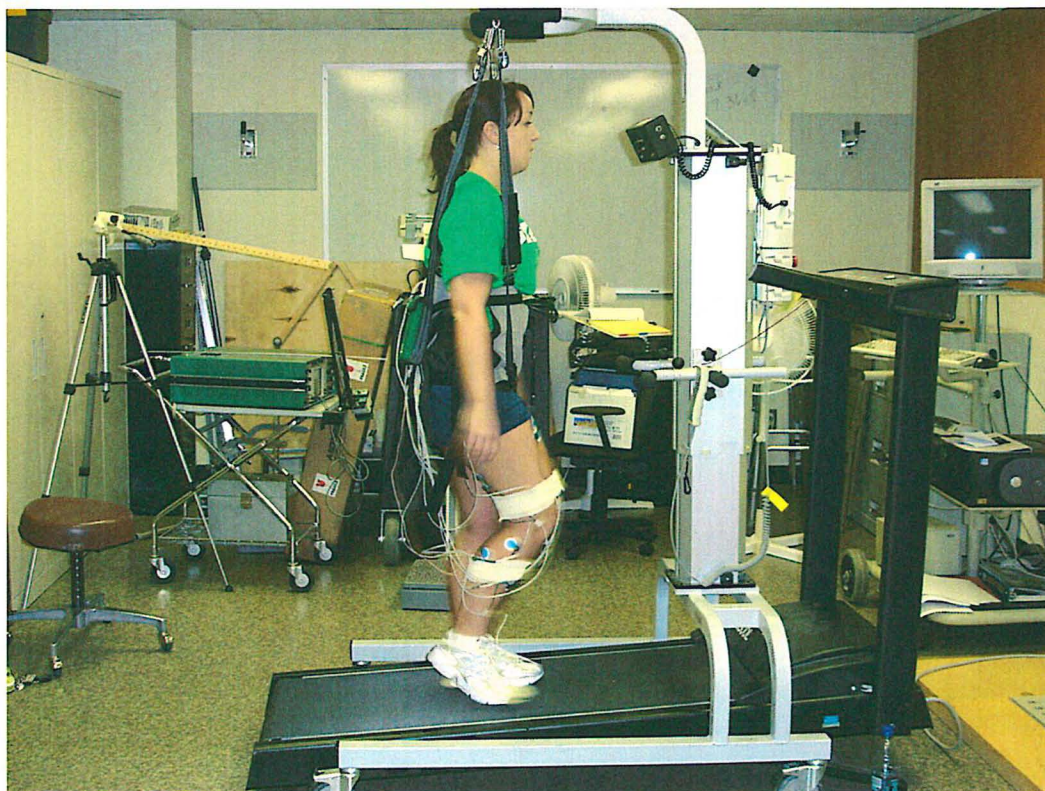


Figure 5. Set-up for the unsupported incline surface trial.



Figure 6. Set-up for the unsupported decline surface trial.

## CHAPTER IV

### RESULTS

The purpose of this study was to collect data on the effects of incline and decline surfaces, combined with partial body weight support, on muscle activity of the lower extremities during treadmill walking for normal subjects. Thus, our research question asked whether there is a difference in EMG activity for the following lower extremity muscles; rectus femoris, gluteus medius, biceps femoris, gastrocnemius, anterior tibialis, and adductor muscle groups, when weight bearing (full or partial) and surface (level, incline, and decline) conditions are varied during forward treadmill ambulation.

Data was collected at two intervals for each condition of the subject's trial. A paired samples t-test was run on SPSS (Version 15.0) in order to determine whether there was a significant difference between the two data intervals of each subject's conditions. Since no significant difference was found between any of the interval pairs, we chose to use the data from the first interval in our statistical analysis. Refer to Table 1 for the results of the paired samples t-test (see Appendix D).

We used a Repeated-Measures ANOVA for comparison of variability between muscle activity in all the conditions. Refer to Tables 3 to 8 for results of the Repeated-Measures ANOVA test results for each muscle group studied. Mauchly's Test of Sphericity was used to determine whether or not sphericity was violated. If Mauchly's sphericity was greater than .05 then sphericity was not violated. When sphericity was violated, or less than .05, the lower-bound analysis was utilized. The Bonferroni test for pair-wise comparisons was used to determine which conditions were significantly

different from the others within each muscle group. In the discussion chapter, greater detail on the conditions determined to be significantly different for each muscle can be found.

Table 2. Repeated-Measures ANOVA Results for Gluteus Medius.

	n	Mean	SD	F	df	p	$\eta^2$	Power
Decline with BWS	20	88.180	38.632	6.239	1, 19	.022	.247	.659
Decline without BWS	20	84.035	20.092	6.239	1, 19	.022	.247	.659
Incline with BWS	20	82.165	22.721	6.239	1, 19	.022	.247	.659
Incline without BWS	20	115.837	35.383	6.239	1, 19	.022	.247	.659
Level with BWS	20	87.703	32.549	6.239	1, 19	.022	.247	.659
Level without BWS	20	84.221	7.129	6.239	1, 19	.022	.247	.659

\*When sphericity was violated, lower bound analysis was utilized



Table 3. Repeated-Measures ANOVA Results for Rectus Femoris.

	n	Mean	SD	F	df	p	$\eta^2$	Power
Decline with BWS	18	68.639	23.853	5.125	5, 85	< .001	.232	.981
Decline without BWS	18	75.543	22.992	5.125	5, 85	< .001	.232	.981
Incline with BWS	18	78.226	20.462	5.125	5, 85	< .001	.232	.981
Incline without BWS	18	91.796	24.111	5.125	5, 85	< .001	.232	.981
Level with BWS	18	67.185	22.191	5.125	5, 85	< .001	.232	.981
Level without BWS	18	74.323	10.593	5.125	5, 85	< .001	.232	.981

Table 4. Repeated-Measures ANOVA Results for the Adductor Group.

	n	Mean	SD	F	df	p	$\eta^2$	Power
Decline with BWS	17	65.220	23.267	8.285	5, 80	< .001	.341	1.000
Decline without BWS	17	70.500	23.665	8.285	5, 80	< .001	.341	1.000
Incline with BWS	17	77.880	19.603	8.285	5, 80	< .001	.341	1.000
Incline without BWS	17	88.943	20.177	8.285	5, 80	< .001	.341	1.000
Level with BWS	17	64.122	19.488	8.285	5, 80	< .001	.341	1.000
Level without BWS	17	74.998	9.660	8.285	5, 80	< .001	.341	1.000

Table 5. Repeated Measures ANOVA Results for the Biceps Femoris.

	n	Mean	SD	F	df	p	$\eta^2$	Power
Decline with BWS	19	70.940	17.615	11.709	1, 18	.003	.394	.899
Decline without BWS	19	68.211	18.185	11.709	1, 18	.003	.394	.899
Incline with BWS	19	104.763	36.402	11.709	1, 18	.003	.394	.899
Incline without BWS	19	99.586	21.390	11.709	1, 18	.003	.394	.899
Level with BWS	19	79.235	21.977	11.709	1, 18	.003	.394	.899
Level without BWS	19	80.068	12.324	11.709	1, 18	.003	.394	.899

\*When sphericity was violated, lower bound analysis was utilized

Table 6. Repeated Measures ANOVA Results for the Lateral Gastrocnemius.

	n	Mean	SD	F	df	p	$\eta^2$	Power
Decline with BWS	20	58.532	11.805	36.795	1, 19	< .001	.659	1.000
Decline without BWS	20	62.240	12.335	36.795	1, 19	< .001	.659	1.000
Incline with BWS	20	71.566	18.907	36.795	1, 19	< .001	.659	1.000
Incline without BWS	20	105.882	28.111	36.795	1, 19	< .001	.659	1.000
Level with BWS	20	64.763	12.933	36.795	1, 19	< .001	.659	1.000
Level without BWS	20	81.907	8.718	36.795	1, 19	< .001	.659	1.000

\*When sphericity was violated, lower bound analysis was utilized

Table 7. Repeated-Measures ANOVA Results for the Anterior Tibialis.

	n	Mean	SD	F	df	p	$\eta^2$	Power
Decline with BWS	19	77.042	17.097	14.930	5, 90	< .001	.453	1.000
Decline without BWS	19	66.744	13.836	14.930	5, 90	< .001	.453	1.000
Incline with BWS	19	77.631	16.913	14.930	5, 90	< .001	.453	1.000
Incline without BWS	19	94.125	19.411	14.930	5, 90	< .001	.453	1.000
Level with BWS	19	80.953	16.694	14.930	5, 90	< .001	.453	1.000
Level without BWS	19	82.635	10.733	14.930	5, 90	< .001	.453	1.000

## CHAPTER V

### DISCUSSION

The purpose of this study was to collect data on the effects of incline and decline surfaces, combined with partial body weight support, on muscle activity of the lower extremities during treadmill walking for normal subjects. Our research question then asked whether there is a difference in EMG activity for the following lower extremity muscles; rectus femoris, gluteus medius, biceps femoris, gastrocnemius, anterior tibialis, and adductor muscle groups, when weight bearing (full or partial) and surface (level, incline, and decline) conditions are varied during forward treadmill ambulation.

For the gluteus medius muscle the condition found to have the greatest amount of muscle activity was the incline without body weight support situation. This condition was found to be significantly different from the decline without body weight support, incline with body weight support and the level without body weight support conditions.

Rectus femoris muscle activity was found to be greatest during the incline without body weight support situation. This condition was found to be statistically significant from conditions of decline with body weight support and level with body weight support.

For the adductor group, the most muscle activity was found during the incline without body weight support condition. This circumstance was found to be significantly different from decline with body weight support and level with body weight support conditions of muscle activity.

Analysis of the biceps femoris muscle activity found two conditions to have the greatest amount of muscle activity: incline with body weight support and incline without

body weight support. Decline with body weight support and decline without body weight support were the two conditions with the least amount of muscle activity making these situations significantly different from the incline with and without body weight support conditions. One potential reason that the biceps femoris muscle showed greatest activity during the incline with body weight support trial could have been due to the placement of the Litegait harness straps over the ischial tuberosities.

The gastrocnemius muscle was found to have the greatest muscle activity during the incline without body weight support situation. This condition was found to be significantly different from all the other conditions, incline with body weight support, level with and without body weight support and decline with and without body weight support.

Analysis of the anterior tibialis muscle activity found incline without body weight support to have the greatest amount of muscle activity. The condition of decline without body weight support was found to have the least amount of muscle activity and was determined to be significantly different from all other conditions.

The condition of incline without body weight support was found to have the greatest muscle activity for all muscles with the exception of the biceps femoris in which it had the second greatest muscle activity. We expect this trend occurred due to the increased demands of working against gravity when ambulating up an inclined surface. Additionally, greater range of motion is required at the hip, knee and ankle for adequate foot clearance over the inclined surface during the swing phase of forward ambulation. Furthermore, due to the increased gravitational demands and decreased forward momentum as compared to ambulation on a level surface, an increased concentric muscle

contraction, and therefore greater muscle activity, is required of the lower extremity musculature.

In an article published by van Hedel, Tomatis and Muller<sup>20</sup> on healthy subjects, it was concluded that standards for EMG activity and joint angle trajectories should only be compared when training is done under conditions of velocities higher than 1.56 miles per hour and less than 50% body weight support. If 75% body weight support or speeds of less than 1.56 miles per hour were used, the cadence and stride length of the subjects' gait was affected. Lower walking speeds also seemed to increase the variability of lower extremity EMG activity between the healthy subjects. Additionally, increased walking speed was demonstrated to be more functional by increasing cadence and stride length. In our study, EMG data collection occurred when subjects were ambulating at a speed of 3.0 miles per hour, which may have helped decrease the variability in lower extremity EMG muscle activity between our subjects. Furthermore, a body weight support of 20% was utilized which could have simulated a more natural walking situation and allowed for normal cadence and stride length to occur. Thus, using 3.0 miles per hour as our ambulation velocity and 20% body weight support for our study parameters may have contributed to the consistent EMG activity we found between subjects in all trials and conditions.

### Limitations

One limitation of this study was the small sample size used. Additionally, the participants we used in the study did not have any physical impairments, giving us data on normal subjects alone. Thus, patients who do have a physical impairment may have differing muscle activities during the conditions studied than those found in our subjects.



Another limitation was that our group of subjects was relatively homogenous being college students of similar age, having similar ethnic backgrounds, and having no history of lower extremity orthopedic surgeries or acute lower extremity injuries. As for the equipment used, we did some isolated problems with the electrodes detecting the muscle activity, which required us to not use certain subject's data for the particular muscle that was affected.

A further limitation was the lack of current literature on the use of body weight support with incline and decline surfaces for all populations, whether normal, neurological or orthopedic. This made it more difficult to choose parameters for the incline and decline surface trials.

### Recommendations

In order to improve upon the study's set-up, we would include a larger sample size. This would allow us more freedom to generalize our results to a larger population and thus make the study more applicable to society. In having a larger sample size we would also want to include subjects of varying ages, ethnicities and backgrounds in order to have a more diverse sample of participants.

By collecting lower extremity EMG data we hope that the information may be applied to the development of treatment alternatives or future research options for both neurological and orthopedic patients. Our study aimed to gather baseline data on muscle activity under different conditions of level, incline and decline and partial or no body weight support situations on subjects without neurological or orthopedic limitations. In order to apply these results to other populations, further research should be done to

evaluate if muscle activity is similarly affected in neurological and orthopedic populations under the conditions studied.

## APPENDIX A

## University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

**Principal Investigator:** Cindy Flom-Meland, Kristin Citterman, Leanne Gere, Jess Price, Kayley Uvaas

Telephone: 777-4130

E-mail Address: cfmeland@medicine.nodak.edu

Complete Mailing Address: P.O. Box 9037

School/College: School of Medicine and Health Sciences

Department: Physical Therapy

**Student Adviser (if applicable):** Cindy Flom-Meland

Telephone: 777-4130

E-mail Address: cfmeland@medicine.nodak.edu

Address or Box #: P.O. Box 9037

School/College: School of Medicine and Health Sciences

Department: Physical Therapy

**Project Title:** The influence of partial body weight support on the muscle activity in normal subjects: on incline/decline surfaces at a constant speed.

**Proposed Project Dates:** Beginning Date: 5/21/07

Completion Date: 5/01/08

(Including data analysis)

**Funding agencies supporting this research:** N/A

**Did the contract with the funding entity go through UND Grants and Contracts Administration?** ☐ YES or ☒ NO

Attach a copy of the contract. Do not include the any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☐ YES or ☒ NO

Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?

☐ YES or ☒ NO

If yes, list all institutions: \_\_\_\_\_

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on letterhead.

Does any external site where the research will be conducted have its own IRB? ☐ YES ☐ NO ☒ N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? ☐ YES ☐ NO ☒ N/A

(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

\_\_\_\_\_ Date submitted: \_\_\_\_\_ Status: ☐ Approved ☐ Pending  
\_\_\_\_\_ Date submitted: \_\_\_\_\_ Status: ☐ Approved ☐ Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

**Type of Project:** Check "Yes" or "No" for each of the following.

- ☒ YES or ☐ NO New Project ☐ YES or ☒ NO Dissertation/Thesis/Independent Study  
☐ YES or ☒ NO Continuation/Renewal ☒ YES or ☐ NO Student Research Project  
Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.  
☐ YES or ☒ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.  
☐ YES or ☒ NO Does your project include Genetic Research?  
☐ YES or ☒ NO Does your project include Internet Research?

**Subject Classification:** This study will involve subjects who are in the following special populations: Check all that apply.

- ☐ Children (< 18 years) ☒ UND Students  
☐ Prisoners ☐ Pregnant Women/Fetuses  
☐ Persons with impaired ability to understand their involvement and/or consequences of participation in this research  
☐ Other \_\_\_\_\_

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

**This study will involve:** Check all that apply.

- ☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements) ☐ Stem Cells  
☐ Radiation ☐ Discarded Tissue  
☐ New Drugs (IND) IND # \_\_\_\_\_ Attach Approval ☐ Fetal Tissue  
☐ Investigational Device Exemption (IDE) # \_\_\_\_\_ Attach Approval ☐ Human Blood or Fluids  
☐ Non-approved Use of Drug(s) ☐ Other \_\_\_\_\_  
☒ None of the above will be involved in this study

### I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

In the past research has been completed on body weight supported gait training with the focus of treating patients with neurological conditions such as SCI, stroke, Parkinson's disease, and Cerebral palsy. However, limited literature and research currently exists on the use of inclined and declined surfaces, in combination with partial body weight support, and how it affects muscle activity of the lower body during treadmill training. In addition, because prior research has focused mainly on patients with neurological involvement the data has not been applied to a broader population; for example, patients completing orthopedic rehabilitation.

The purpose of this study is to collect baseline data on the effects of incline/ decline surfaces with partial body weight support on muscle activity of the lower extremities in normal subjects during treadmill walking. This information may allow for possible treatment alternatives or future research options for neurological patients and also may provide EMG data that can be applied to patients with orthopedic conditions as well.

## **II. Protocol Description**

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories.

### **1. Subject Selection.**

- a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

Subjects will be recruited from the University of North Dakota. Sign up sheets will be posted in the School of Medicine and Health Sciences and in the Memorial Union building. Subjects will be recruited for a one time commitment. It will be a sample of convenience with a goal of at least 30 subjects. A sample of the sign-up sheet is attached for review.

- b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

All subjects must be 18 years of age or older, students at the University of North Dakota, and be able to fulfill the one time commitment required.

- c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

Subjects will be excluded if they have a history of orthopedic surgery, current sub acute injuries (within 8 weeks of data collection), as these will be considered exclusion criteria for this study. This population will be excluded due to the potential for altered muscle activity from impaired kinematics.

- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

This study will include a sample of convenience with a goal of 30 subjects. This will enable us a large enough sample to potentially generalize the results to a greater population.

- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

Power analysis was not completed for this procedure.

### **2. Description of Methodology.**

- a) Describe the procedures used to obtain informed consent.

Each subject will be given an information and consent form to be completed prior to participation in the study. Subjects will be asked to read and sign the consent form indicating they understand the requirements of participation. A copy of the information and consent form will be provided to the participant. The subject has the right to terminate participation in the study at any time.

- b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

The research will be conducted in the University of North Dakota Physical Therapy Department. A GateKeeper treadmill with a LiteGait harness will be used for partial body weight support ambulation. A BiSym scale will be used to record the weight of each participant and a TeleMyo 900 telemetry unit will be used to collect EMG activity. Equipment will be available in the department when needed.

- c) Indicate who will carry out the research procedures.

The four student researchers and the student advisor, along with two UND PT faculty members.

- d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

After obtaining informed consent, EMG electrode placements will be determined and marked on each participant on the @ lower extremity with a permanent marker. The electrode site will be prepared by shaving the area and cleaning the site with rubbing alcohol, in order to allow the electrodes complete contact with the skin. Two electrodes will be placed 1-2 mm apart on each muscle to be tested, parallel to the muscle fibers. The recorded muscles include the gluteus medius, rectus femoris, adductor magnus, biceps femoris, vastus medialis, anterior tibialis and gastrocnemius.

Subjects will then be put in the LiteGait harness and once the participant is on the treadmill, the electrodes will be connected to their corresponding wire and all EMG equipment will be hooked up prior to weighing. The participant's full body weight will then be taken using the BiSym scale and body weight will be recorded. 30% or less of body weight support will be calculated based on this figure.

Baseline performance on a level surface will be performed first for all participants and performance of incline and decline will be randomly assigned. Each subject will then ambulate for 3 minutes for each trial of level surface, incline and decline. To begin each trial the subject will be given one minute to increase their speed on the treadmill to no more than 5.0 mph (exact speed will be standardized and has not yet to be determined). This will allow the subject time to become familiar with the treadmill. At each trial; level surface, incline and decline, each subject will ambulate with full body weight support first, followed by partial body weight support ambulation. Incline and decline will be standardized and not exceed a 10.0 grade. During the second and third minutes of each trial, 10 second intervals will be randomly selected to collect muscle activity data. Between each trial subjects will be able to rest for 1-2 minutes while the surface level is modified.

- e) Describe audio/visual procedures and proper disposal of tapes.

N/A

- f) Describe the qualifications of the individuals conducting all procedures used in the study.

All four student researchers are enrolled in the University of North Dakota Physical Therapy program and have received instruction in the use of all equipment and tools used in this study. Faculty members and the student advisor will be assisting with the study and are skilled in the operation of all necessary equipment. In addition, all researchers are CPR certified.

- g) Describe compensation procedures (payment or class credit for the subjects, etc.).

N/A

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

### 3. Risk Identification.

- a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

Generally, when using exercise equipment a small risk for minor injury is possible, including fatigue and muscle strain. However, this study utilizes a low level of exertion which decreases the possibility of such risks occurring. Subjects may experience mild skin irritation following preparation, application and removal of EMG electrodes to the skin.

- b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

All data and consent information will be kept separately to ensure subject confidentiality.

- c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.

N/A

- d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.

N/A

#### 4. Subject Protection.

- a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Each subject will have individual EMG electrodes and hair removal devices (i.e. clippers). They will also be informed of the potential for minor skin irritation from the electrode adhesive and possible injury with use of the treadmill. Education on the safety mechanisms and use of the treadmill will take place for each participant prior to data collection.

- b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

To ensure confidentiality, consent forms and data will be kept separately and only the participant and researchers will be allowed in the room during data collection. Subjects will be assigned a number to correlate with their data, and the master list of names and assigned numbers will be kept separately from the data.

- c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

Prior to data collection, each subject will be provided with a consent form to sign and information on how the study will be conducted. A copy of the information will be available upon request of the participant.

- d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.  
Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)  
2) who will have access to the data  
3) how the data will be destroyed



- 4) the storage location of consent forms and personal data (separate from research data)
- 5) how the consent forms will be destroyed

The research data collected will be stored in the physical therapy department at UND in locked file cabinets in a locked room. Only the researchers (Cindy Flom-Meland, Kristin Citterman, Leanne Gere, Jess Price and Kayley Uvaas) will have access to these files at any time. After 3 years, the research data will be shredded and destroyed. The consent forms and personal data will be kept separately from the research data in locked files in a locked room of the physical therapy department at UND. After 3 years, the consent forms and personal data will be shredded and destroyed.

- e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

In the event of an injury, medical attention will be available to the participant. All expenses incurred through medical treatment will be the responsibility of the participant and/or third party payors.

- f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

In the event of an injury, medical attention will be available to the participant. All expenses incurred through medical treatment will be the responsibility of the participant and/or third party payors.

### **III. Benefits of the Study**

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

The purpose of this study is to collect baseline data on the effects of incline/ decline surfaces with partial body weight support on muscle activity of the lower extremities in normal subjects during treadmill walking. This information may allow for possible treatment alternatives or future research options for neurological patients and also may provide EMG data that can be applied to patients with orthopedic conditions as well. The significance of this study is the attempt to bridge the gap between the uses of partial body weight support treadmill training (PBWSTT) on incline/ decline surfaces between orthopedic and neurological patients.

### **IV. Consent Form**

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. **Please note:** All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. **The consent form should be written at no higher than an 8<sup>th</sup> grade reading level**, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

#### **Necessary attachments:**

- ☐ Signed Student Consent to Release of Educational Record Form (students only);
- ☐ Investigator Letter of Assurance of Compliance;
- ☐ Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- ☐ Surveys, interview questions, etc. (if applicable);
- ☐ Printed web screens (if survey is over the Internet); and
- ☐ Advertisements.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached

information is accurate and that the project will be completed as indicated.

**Signatures:**

---

(Principal Investigator)

Date:

---

(Student Adviser)

Date:

**Requirements for submitting proposals:**

Additional information can be found on the IRB web site at [www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html](http://www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html).

Original Proposals and all attachments should be submitted to Research Development and Compliance, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to <http://www.und.edu/dept/rdc/regucomm/IRB/IRBEducation.htm> for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the RD&C website regarding required copies and IRB review categories, or you may call the RD&C office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

## APPENDIX B

## INFORMATION AND CONSENT FORM

The influence of partial body weight support on the muscle activity in normal subjects: on incline/ decline surfaces at a constant speed.

You are invited to participate in a research study conducted by Cindy Flom-Meland, a physical therapy professor at the University of North Dakota, and Kristin Citterman, Leanne Gere, Jess Price, and Kayley Uvaas, students of physical therapy at the University of North Dakota. The purpose of our study is to analyze the effect of partial body weight support on the muscle activity in normal subjects: on incline/ decline surfaces at a constant speed.

You will be excluded from this study if you have a history of orthopedic surgery, current sub acute injuries (within 8 weeks of data collection), as these will be considered exclusion criteria for this study. You must also be a student at the University of North Dakota and be at least 18 years of age.

In order to participate in this study, you will need to be able to commit to a one-time, one hour time period. During this hour, you will be expected to walk on a treadmill at no more than 5 miles per hour, and at an incline/decline of no more than a 10% grade, for 25-30 minutes. The remainder of the time will be used for electrode placement, treadmill set-up and warm-up time. Electrodes will be placed on various muscles of the right hip and leg and you will be required to wear shorts and a pair of tennis shoes or comfortable walking shoes. Your participation in this study will allow us to determine whether or not muscle activity varies under circumstances of partial body weight support and on incline/decline surfaces. Your results will benefit future researchers when they are using partial body weight support and incline/decline treadmill training for patients with neurological and orthopedic disabilities.

This treadmill activity is considered to be a low-risk activity; however, with any type of exercise, there may be minimal risk of injury. The electrodes used may cause minor skin irritation, and the area it will be applied to must be shaved and prepared for electrode placement. We intend to minimize these risks by providing you with proper time to become comfortable on the treadmill and with the equipment used. In the event of injury, medical treatment will be available as it is to a member of the general public in similar circumstances. Payment for medical treatment will be covered by you and your third party payer. By signing this document, you are not giving up any legal rights you may have in the case of negligence or other legal fault of anyone that is involved in the study.

The information and data collected in this study will be kept confidential. Your name and identifying information linking you to this study will not be revealed at any time, and all data will be kept separate from your name and consent forms. The results from this study will be kept in a secure, locked cabinet in the Physical Therapy Department at the University of North Dakota. The only people with access to the results will be the researchers named above and the individuals at the University of North Dakota who audit research projects on campus. They will be destroyed three years after the study is closed.

There will be no financial compensation awarded to either you or the researchers conducting the study.

Participation in this study is completely voluntary. Your decision whether or not to participate will not change your future relations with the University of North Dakota. If you decide to participate, you or the investigators can choose to withdraw participation in the study at any time without penalty.

If you have any questions or concerns regarding this study, please feel free to contact Cindy Flom-Meland at the University of North Dakota at 777-4130. You can also reach any of the student researchers through the Department of Physical Therapy at the University of North Dakota between the office hours of 8:00 AM to 4:30 PM at 777-2831. If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279. Please call this number if you cannot reach research staff or you wish to talk with someone else.

I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND WILLINGLY AGREE TO PARTICIPATE IN THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. A COPY OF THIS CONSENT FORM HAS BEEN GIVEN TO ME.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date

## APPENDIX C



Figure 7. Gluteus medius electrode placement.



Figure 8. Rectus femoris electrode placement.



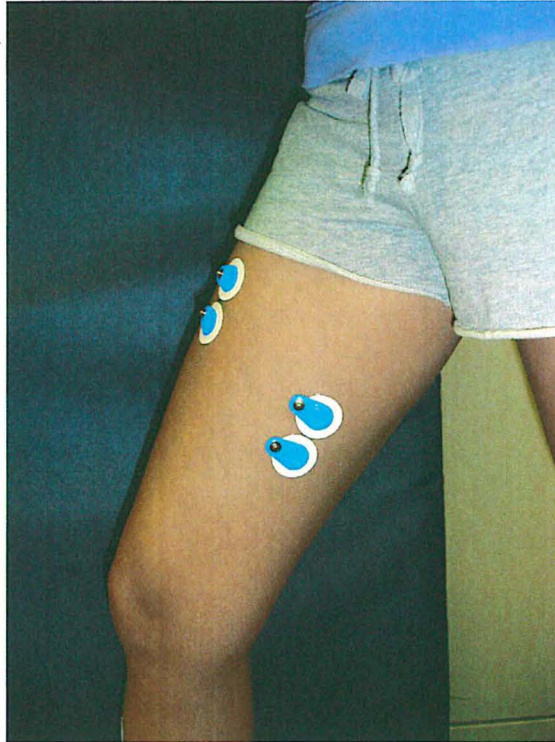


Figure 9. Adductor group electrode placement.

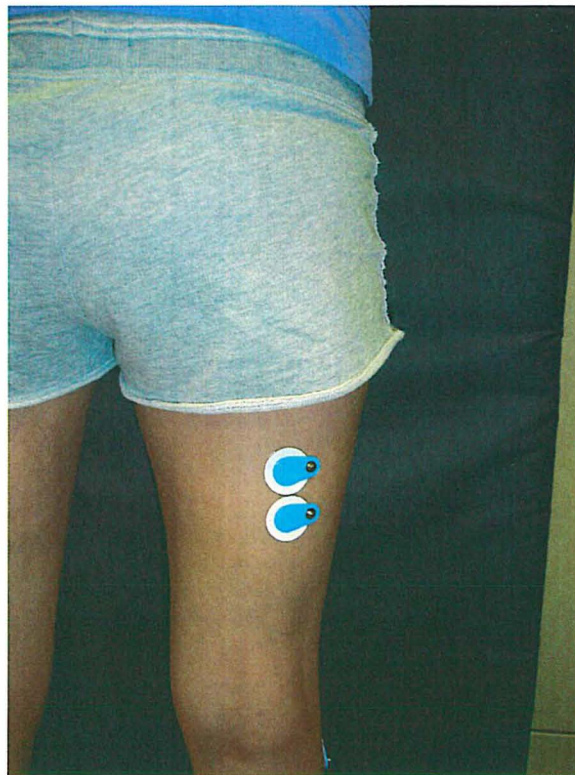


Figure 10. Biceps femoris electrode placement.





Figure 11. Lateral gastrocnemius electrode placement.

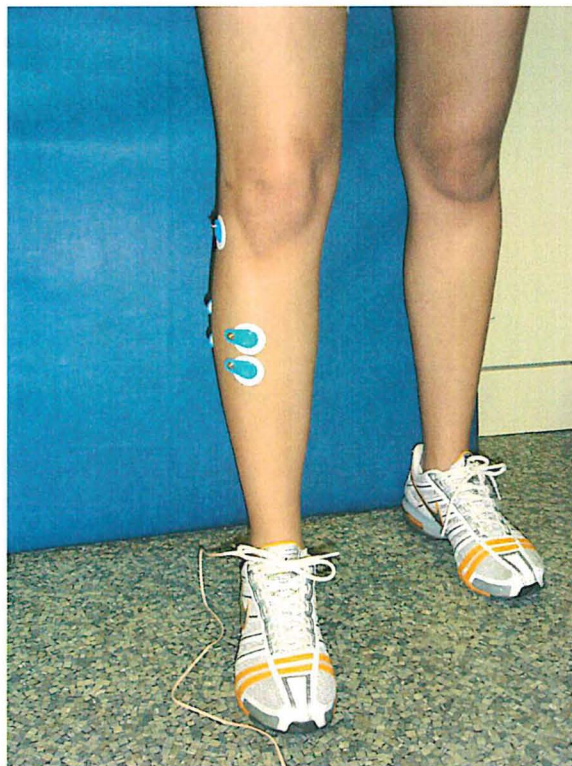


Figure 12. Anterior tibialis electrode placement.

## APPENDIX D

Table 1. T-Test paired sample statistics

Muscle Group	n	Condition	Mean	SD	t	df	p
Gluteus Medius	20	Decline with support, trial 1	88.180	38.632	1.956	19	.065
	20	Decline with support, trial 2	82.910	37.132	1.956	19	.065
	20	Decline without support, trial 1	84.035	20.092	-1.481	19	.155
	20	Decline without support, trial 2	87.260	21.428	-1.481	19	.155
	20	Incline with support, trial 1	82.165	22.721	.346	19	.734
	20	Incline with support, trial 2	81.123	23.109	.346	19	.734
	20	Incline without support, trial 1	115.837	35.383	-.437	19	.667
	20	Incline without support, trial 2	117.105	33.498	-.437	19	.667
	20	Level with support, trial 1	87.703	32.549	.880	19	.390
	20	Level with support, trial 2	84.602	28.642	.880	19	.390

Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Gluteus Medius	20	Level without support, trial 1	84.221	7.129	.157	19	.877
	20	Level without support, trial 2	83.756	10.020	.157	19	.877
Rectus Femoris	19	Decline with support, trial 1	69.172	23.297	-.888	18	.386
	19	Decline with support, trial 2	72.361	28.227	-.888	18	.386
	19	Decline without support, trial 1	72.812	22.570	-1.278	18	.218
	19	Decline without support, trial 2	74.812	22.570	-1.278	18	.218
	19	Incline with support, trial 1	78.872	19.469	-.244	19	.810
	19	Incline with support, trial 2	79.867	26.374	-.244	19	.810
	19	Incline without support, trial 1	92.804	23.840	.377	18	.711

Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Rectus Femoris	19	Incline without support, trial 2	91.033	20.185	.377	18	.711
	19	Level with support, trial 1	69.790	23.524	-1.220	19	.237
	19	Level with support, trial 2	74.330	27.491	-1.220	19	.237
	19	Level without support, trial 1	74.839	10.304	-.524	19	.607
	19	Level without support, trial 2	77.938	24.508	-.524	19	.607
Adductors	20	Decline with support, trial 1	68.139	24.632	-1.338	18	.197
	20	Decline with support, trial 2	73.607	35.932	-1.338	18	.197
	20	Decline without support, trial 1	69.722	23.195	-1.613	17	.125
	20	Decline without support, trial 2	74.682	28.962	-1.613	17	.125

Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Adductors	20	Incline with support, trial 1	77.990	18.533	-.259	18	.799
	20	Incline with support, trial 2	78.868	24.933	-.259	18	.799
	20	Incline without support, trial 1	90.072	20.152	-.370	17	.716
	20	Incline without support, trial 2	91.594	17.953	-.370	17	.716
	20	Level with support, trial 1	67.025	20.149	-1.580	19	.131
	20	Level with support, trial 2	72.050	24.123	-1.580	19	.131
	20	Level without support, trial 1	76.153	10.282	-.125	19	.902
	20	Level without support, trial 2	76.770	19.964	-.125	19	.902
Biceps Femoris	20	Decline with support, trial 1	73.122	19.726	.688	19	.500
	20	Decline with support, trial 2	70.667	17.642	.688	19	.500

Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Biceps Femoris	20	Decline without support, trial 1	68.078	17.710	.556	19	.585
	20	Decline without support, trial 2	67.220	17.811	.556	19	.585
	20	Incline with support, trial 1	106.208	36.016	1.856	19	.079
	20	Incline with support, trial 2	99.140	32.521	1.856	19	.079
	20	Incline without support, trial 1	101.640	22.756	-.346	19	.733
	20	Incline without support, trial 2	102.597	21.110	-.346	19	.733
	19	Level with support, trial 1	79.235	21.977	-.653	18	.522
	19	Level with support, trial2	80.768	18.541	-.653	18	.522
	20	Level without support, trial 1	79.532	12.233	.589	19	.563

Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Biceps Femoris	20	Level without support, trial 2	76.503	21.109	.589	19	.563
Gastrocnemius	20	Decline with support, trial 2	58.532	11.805	.767	19	.453
	20	Decline without support, trial 1	62.240	12.335	-.078	19	.938
	20	Decline without support, trial 2	62.382	13.482	-.078	19	.938
	20	Incline with support, trial 1	71.566	18.907	-.620	19	.543
	20	Incline with support, trial 2	72.502	20.668	-.620	19	.543
	20	Incline without support, trial 1	105.882	28.111	-.985	19	.337
	20	Incline without support, trial 2	108.840	26.650	-.985	19	.337
	20	Level with support, trial 1	64.763	12.933	.065	19	.949



Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Gastrocneumius	20	Level with support, trial 2	64.642	14.598	.065	19	.949
	20	Level without support, trial 1	81.907	8.718	1.173	19	.255
	20	Level without support, trial 2	77.918	11.556	1.173	19	.255
Anterior Tibialis	19	Decline with support, trial 1	77.042	17.097	.149	18	.883
	19	Decline with support, trial 2	76.728	17.056	.149	18	.883
	20	Decline without support, trial 1	66.345	13.585	.579	19	.569
	20	Decline without support, trial 2	65.408	15.086	.579	19	.569
	20	Incline with support, trial 1	78.456	16.870	-.574	19	.573
	20	Incline with support, trial 2	79.640	18.261	-.574	19	.573

Table 1. T-Test paired sample statistics continued.

Muscle Group	n	Condition	Mean	SD	t	df	p
Anterior Tibialis	20	Incline without support, trial 1	94.522	18.976	.516	19	.612
	20	Incline without support, trial 2	92.457	16.085	.516	19	.612
	20	Level with support, trial 1	80.030	16.764	2.030	19	.057
	20	Level with support, trial 2	75.833	17.903	2.030	19	.057
	19	Level without support, trial 1	79.377	17.371	.369	18	.716
	19	Level without support, trial 2	77.451	10.697	.369	18	.716

## APPENDIX E

## RELEASE STATEMENT

I hereby give my permission to the University of North Dakota, its agents, successors, assigns, clients and purchasers of its services and/ or products , to use my photograph (whether still, motion, or television).

Name: \_\_\_\_\_

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

State and Zip Code: \_\_\_\_\_

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